

- Appl. No. 09/922,604
- Amendment dated September 24, 2004
- Reply to Office Action mailed April 7, 2004

### **REMARKS/ARGUMENTS**

Claims 21-29 are pending. Claims 1-20 have been cancelled without intending to abandon or to dedicate to the public any patentable subject matter. As set forth more fully below, reconsideration and withdrawal of the Examiner's rejections of the claims are respectfully requested.

#### **Rejections Under 35 U.S.C. § 101**

Claims 1 and 11 were rejected under 35 U.S.C. § 101 as lacking a well supported utility. Claims 1 and 11 have been cancelled. New claims 24 and 25 do not recite "preventing" unwanted side reactions. Thus, Applicants submit that new Claims 24 and 25 meet the requirements of 35 U.S.C. §§ 101 and 112, first paragraph.

#### **Rejections Under 35 U.S.C. § 112, First Paragraph**

The Examiner has rejected Claims 1 and 11 under 35 U.S.C. § 112, first paragraph, as lacking enablement for R<sup>5</sup> groups other than benzyl. Applicants have cancelled Claims 1 and 11. New Claim 21 incorporates the limitations of cancelled claims 1, 5, 6 and 8. However, new Claim 21 recites an R<sup>5</sup> group of benzyl and is subsequent removal by hydrogenation. For this reason, Applicants submit that new Claim 21 is sufficiently enabled by the specification to meet the requirements of 35 U.S.C. § 112, First Paragraph.

#### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected Claims 1-20 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Examiner notes that Claim 1 recites "unwanted" side reactions and refers to "formula 2" which is not shown in the claims. Claims 1-

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20 have been cancelled. New Claim 21 has been drafted to include the limitations of Claims 1, 5, 6 and 8. Claim 21 does not recite unwanted side reactions or refer to formulas or structures that are not specifically shown in the claim. Applicants therefore submit that new Claims 21-29 are sufficiently definite to meet the requirements of 35 U.S.C. § 112, second paragraph.

Claim Rejections Under 35 U.S.C. § 102

The Examiner has rejected Claims 1, 3, 8 and 9 under 35 U.S.C. § 102(b) as being anticipated by PCT publication No. WO 96/10396 or WO 9609813 (hereinafter "Milstein"). Milstein discloses the preparation of a diketopiperazine of glutamic acid. Milstein teaches a synthesis procedure carried out at 0°C and acidified with with trifluoroacetic acid (see, for example, WO 96/10396 page 13, lines 4-15). Applicants have cancelled Claims 1, 3, 8 and 9. New claim 21 recites the use of a neutral solvent at a temperature between 80°C and 180°C. Support for these limitations can be found in the specification at least at page 7, lines 6-15. Thus, Milstein does not anticipate new claims 21-29. Applicants therefore respectfully request the Examiner's rejection under 35 U.S.C. § 102(b) be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

The Examiner has rejected Claims 11, 15 and 16 under 35 U.S.C. § 103(a) as being obvious over Bioorg. Med. Chem. Lett. 8, 2369, 1998 (hereinafter "Smith"). Smith discloses the production of a diketopiperazine on a solid support. Applicants have cancelled Claims 11, 15 and 16. New Claim 29 is directed to the embodiment of the present invention in which the diketopiperazine is synthesized on a solid support. Claim 29 depends from Claim 21 and therefore incorporates all of the limitations of Claim 21. Similar to the rejection under Milstein discussed above, Smith discloses the use of acidic solutions (Scheme 1, TFA and AcOH) during

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the single cyclization and removal step. Thus, Claim 21 is not anticipated nor rendered obvious by Smith. Therefore, Applicants submit that Smith does not teach all of the limitations of the pending claims and respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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